

Atty. Dkt. 070441/0274072  
WOOLF et al. Appln. No. 09/778,956

### REMARKS

Claim 24 is amended to increase clarity and not for any reason of patentability. Claims 42-45 are new. Claims 1-45 are pending. Reconsideration and allowance of the present application based on the following remarks is respectfully requested.

Claims 1-23 were rejected under 35 U.S.C. § 101. During a telephone interview on August 11, 2004 (reported separately), the Examiner suggested that the Federal Circuit decision in Affymetrix, and the discussion of this decision in MPEP 2106.IV.B.2.(b)(i), part 2, support requiring the recitation of a physical transformation for patentability. For at least the reasons below, applicants respectfully request reconsideration of this position.

For reference, the following claim was deemed patentable in Affymetrix:

1. A method for analyzing electrocardiograph signals to determine the presence or absence of a predetermined level of high frequency energy in the late QRS signal, comprising the steps of:

converting a series of QRS signals to time segments, each segment having a digital value equivalent to the analog value of said signals at said time;

applying a portion of said time segments in reverse time order to high pass filter means;

determining an arithmetic value of the amplitude of the output of said filter; and

comparing said value with said predetermined level.

Applicant respectfully notes that the "converting" step recited in the Affymetrix claim is expressly limited to converting an analog signal into a digital signal: a process also known as "sampling." Therefore, this step does not recite any transformation of data from outside the computer to inside the computer and merely sets forth a manipulation of data. Applicant respectfully notes that the pending claims also recite data manipulation operations: e.g. the "fuzzifying" operation recited in claim 1, and the operation of obtaining a plurality of qualitative descriptors in claim 24.

In discussing this claim, the MPEP states the following: "The transformation occurs when heart activity is measured and an electrical signal is produced." Applicant respectfully

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notes that these operations are not recited in the Affymetrix claim. Although existence of the data indicates that such a transformation did occur (as is the case in applicant's pending claims), this claim does not recite it. Rather, it recites operations on the signal subsequent to the cited transformation. Therefore, this section of the MPEP cannot be said to support the proposed requirement of reciting a physical transformation. In fact, this section teaches the patentability of claims that recite "Manipulation of Data Representing Physical Objects or Activities," and applicant's pending claims recite such manipulation.

This section also states that "This process has real world value in predicting vulnerability to ventricular tachycardia immediately after a heart attack." Applicant respectfully notes that these aspects of the invention also are not recited in the Affymetrix claim, which ends with merely comparing a value of a filtered signal to a predetermined value. Presumably, this teaching appears elsewhere in the application, such that with reference to the supporting written description, one of ordinary skill in the art would appreciate the cited utility. See, e.g., MPEP 2107.II.(B). Likewise, demonstration of the real world value of applicant's claimed method may be found at, e.g., page 19, line 6 to page 24, line 9, and also at lines 7-18 of page 26, of the specification as originally filed.

Applicant notes that the second example cited in this section is the following claim from In re Abele and Marshall, 214 USPQ 682 (CCPA 1982):

6. [A method of displaying data in a field comprising the steps of  
calculating the difference between the local value of the data at a data  
point in the field and the average value of the data in a region of the field which  
surrounds said point for each point in said field, and  
displaying the value of said difference as a signed gray scale at a point in  
a picture which corresponds to said data point]  
wherein said data is X-ray data attenuation data produced in a two  
dimensional field by a computed tomography scanner.

In discussing this claim, the MPEP states the following: "The transformation occurs when the condition of the human body is measured with X-rays and the X-rays are converted into electrical digital signals that represent the condition of the human body." Again, the cited transformation is not recited in the claim. The claim recites manipulating data that explicitly

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represents a physical activity, but it does not recite the transformation that gave rise to such data. Applicant respectfully submits that requiring the recitation of such a transformation for patentability would be contrary to the teachings of the MPEP.

With reference to the Abele claim above, this section also states that "The real world value of this invention lies in creating a new CAT scan image of body tissue without the presence of bones." Applicant respectfully notes that neither body tissue nor bones are recited in this claim, although presumably such use of the claimed invention is sufficiently disclosed to the artisan by the specification of that application. See, e.g., MPEP 2107.II.(B) cited above.

Therefore, Applicants respectfully submit that the subject matter of claims 1-41 is statutory as required under 35 U.S.C. § 101, and respectfully request reconsideration and withdrawal of this rejection.

#### New Claims

Claims 42-44 recite that the data point indicates a quality of a gene or protein. Claim 45 recites that the predicted value indicates a direction and/or magnitude of regulation of, e.g., an amino acid sequence. Disclosure of such features may be found in the specification as originally filed at, e.g., page 13. Applicant respectfully submits that these claims are allowable at least for the reasons set forth herein.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in a condition for allowance and a Notice to that effect is earnestly solicited. If any point remains in issue which the Examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number listed below.

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Please charge any fees associated with the submission of this paper to Deposit Account Number 03-3975 under Order No. 070441/0274072. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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Date: September 10, 2004

Customer Number [00909]

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re PATENT APPLICATION OF

Confirmation No.: 5820

WOOLF et al.

Group Art Unit: 1631

Appln. No.: 09/778,956

Examiner: Marschel, Ardin H.

Filed: February 8, 2001

Title: A METHOD FOR ANALYZING GENE EXPRESSION DATA USING FUZZY LOGIC

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**SUMMARY OF TELEPHONIC INTERVIEW**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicant presents the following summary of an interview in this application between Examiner Marschel and applicant's undersigned representative, conducted by telephone on the morning of Wednesday, August 11, 2004. Applicant notes with appreciation the Examiner's review, in advance of the interview, of the Amendment filed July 29, 2004.

The Examiner agreed that the rejection under section 112 would be withdrawn. The rejection under section 101 was then discussed. The Examiner suggested that the Affymetrix claim (used as an example in the MPEP and in applicant's amendment) supported the rejection because this claim recites a conversion of the data from outside the device to inside the device.

Applicant's representative responded by noting that the section of the MPEP which cites the Affymetrix claim is headed "Manipulation of Data Representing Physical Objects or Activities" (MPEP 2106.IV.B.2.(b)(i), part 2) and that the pending claims are clearly limited to manipulation of data representing physical objects or activities. Applicant's representative argued that the pending claims thus satisfy the requirements of this section, and that the proposed additional requirement of a conversion of data from outside to inside is not supported in this section of the MPEP.

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The Examiner indicated that another section of the MPEP was relevant to this inquiry: the noise example presented at MPEP 2106.IV.B.2.(b)(ii). The Examiner suggested that this example supported the proposed requirement that a patentable claim must recite a physical transformation. The Examiner explained that a claim for an algorithm for modeling noise is nonstatutory because it does not recite any way for making the noise e.g. perceptible, as one example of a physical transformation.

Applicant's representative noted that the example deemed statutory — a process for filtering noise using such an algorithm — also does not recite perceptibility or any other physical transformation. Applicant's representative noted that the dichotomy being presented in this example is between the nonstatutory algorithm (or "law of nature") on one hand, and the statutory process for using such an algorithm on the other. Applicant's representative noted that indeed this section is headed "Computer-Related Processes Limited to a Practical Application in the Technological Arts," and that no requirement of perceptibility or physicality is supported in this section either.

In response to this observation, the Examiner questioned whether the pending claims are limited to a practical application. Applicant's representative noted that claim 1 recites that the data being manipulated represent regulation of genes or proteins, which definitively limits the claimed process to a practical application. The Examiner responded that the process recited in claim 1 merely determines a confidence level of a predicted value, and suggested that this was not a practical application. Applicant's representative agreed with the statement that the process determines such a confidence level, and submitted that the claimed process is nevertheless limited to a practical application at least by the recited manipulation of data representing regulation of genes or proteins.

Applicant's representative then asked whether the Examiner would raise the same objection to claim 24, which recites that the predicted value whose confidence level is determined relates to, e.g. another sequence of nucleic acids. The Examiner stated that this recitation was also insufficient, and that patentability would require the further recitation of display of the data, or some other act of making the data perceptible or otherwise bringing it into the "real world," e.g. a recitation of a physical transformation. The Examiner then concluded the interview.

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At the conclusion of the interview, applicant's representative promised to forward to the Examiner an identification of several art units that specialize in examination of claims relating to data analysis. Applicant's representative believes that the following Art Units deal primarily with data analysis: 2654, 2171, 2176, 2787 (relating to technical applications) and 3621-3627 (relating to business applications).

Respectfully submitted,  
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